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Appl. No. : 10/806,828 Confirmation No. 4223  
Applicant : Svava Maria Atladottir et al.  
Filed : March 22, 2004  
Art Unit : 3731  
Examiner : Elizabeth Houston  
Title : SELF-EXPANDING STENT AND CATHETER  
ASSEMBLY AND METHOD FOR TREATING  
BIFURCATIONS

Docket No.: : ACS.64880 (G2625USP3)  
Customer No. : 68919 October 4, 2010

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

REPLY BRIEF

This Reply Brief is responsive to the Examiner's Answer mailed August 5, 2010 in the appeal from the Final Office Action mailed November 6, 2009. This Reply Brief is being filed within the term provided as permitted under 37 C.F.R. § 1.193(b)(1), and is in compliance with 37 C.F.R. § 41.37.

## ARGUMENT

### GROUND I

In the 'Response to Arguments' relating to the Vardi rejection, the Examiner attempts to apply the catch-all paragraph present in the reference (page 12, lines 22-25) that generally states that the stents may be deployed "by any method currently known or developed in the future which is effective for expanding the stents of the invention", including the use of balloons and self-expansion, to the specific embodiment (Figure 10) that is relied upon by the Examiner to reject the claims. The overlooked portion of such statement is however the proviso that the method must be "effective for expanding the stents of the invention." In view of the fact that the stent configuration shown in Figure 10 that is relied upon by the Examiner must first be radially expanded after which the loops 106 are to be laterally extended into a side branch, it is not clear how such combination of distortions can be achieved by self-expansion. As a consequence, self-expansion is not an effective mechanism for deploying the stent of Figure 10 and the reference therefore fails to suggest let alone anticipate a self-expanding stent with peaks that flare radially outwardly (as opposed to peaks that must **be flared** radially outwardly) into a side branch. Contrary to the Examiner's assertion that Vardi explicitly states that a particular embodiment can be self-expanding, it is respectfully submitted that Vardi merely states that self expansion can be relied upon for the deployment of those stent configurations for which it is effective. There is no indication that the peak **and** loop combination of Figure 10 can be deployed by self-expansion.

The Examiner then argues that "it is irrelevant how the stent achieves its final shape as long as the final shape has the portions flared radially outwardly."

Appellants respectfully traverse. A structure that must be flared radially outwardly differs from a structure that flares radially outward. The claims are not directed to the final shape of the stent, i.e. the claims are not directed to a stent having radially outwardly flared peaks. Rather, the claims are directed to a stent configuration with a certain capability, namely one that self-expands and further, one that self-expands with peaks that flare radially outwardly.

The Examiner goes on to "strongly disagree" with the significance of the specific claim language that is used with respect to the "first" peaks. The claims clearly call for stent to have a proximal, central and distal section each with a number of 'first' peaks therein wherein the number of 'first' peaks in the central section differ so as to provide additional coverage. Such claim language not only implicitly but explicitly requires the peaks to be the same and precludes an interpretation so as to include completely different peaks having different shapes, sizes, and orientations in the peak count (as per the cited reference), most especially when interpreted in light of the disclosure. If the intention had been that the peak count was to have included any and all peaks in a ring, there would have been absolutely no reason to include the term 'first' ring. The Examiner's assertion that "the use of the term 'first' is merely interpreted as an identifier that groups a number of the peaks together," is precisely what was intended, i.e. a specific group of peaks (i.e. those that are similar) rather than all the peaks in a ring. The cited reference clearly fails to suggest having the ring count of 'first' rings in the central section differ so as to provide additional material for apposing a side branch vessel upon flaring thereinto.

## GROUND II

In the 'Response to Arguments' relating to the obviousness rejection, the Examiner argues that simply using a self-expanding material to form the stent shown in the Vardi reference would obviously cause it to self-expand while its loops flare radially outwardly into the opening of the side branch. The Examiner then relies on the wholly unsupported statement that "there are numerous patents that use self-expanding material to expand stents with flared portions at an ostium or branched vessel," yet fails to cite a single such reference. Moreover, as had repeatedly been argued, the present invention is not directed to a stent configuration that merely self-expands **with flared portions**, but rather a self-expanding stent configuration with peaks that are "**configured to flare** radially outwardly into an opening to the side branch." While the Examiner may insist that this argument is "irrelevant," the appellant respectfully submits that the choice of claim language was not incidental and that the disclosure fully supports the notion that "configured to flare" is not the equivalent of merely a "flared" configuration. As a result, and contrary to the Examiner's assertion, the present invention is a clear departure from a stent having a configuration wherein the main branch portion is self expanding while the flared portion must be expanded with the use of a balloon as per the Vardi reference.

## GROUND III

In the 'Response to Arguments' relating to the coated stent claims, the Examiner asserts that "it is old and well known in the art to incorporate shape memory material into stents in order to form a desired expanded shape." As had previously been argued, there is however no evidence that it is old and well known in the art how the use of shape memory material would cause a stent to first expand

and then have peaks in the center of the stent flare radially outwardly into a side branch. The primary reference that the Examiner is relying on fails to provide any teaching in that regard as the described stent configuration requires the use of a balloon to flare peaks into a side branch opening after self-expansion may (or may not) be relied upon to simply expand the main body of the stent. No suggestion is made in any combination of the references that are actually cited by the Examiner of a self-expanding stent configuration having a central section with additional 'first' peaks that flare (rather than having **to be flared**) into a side branch opening upon deployment of the stent. In the absence of any such teaching or suggestion, it is respectfully submitted that obviousness is effectively avoided

## **CONCLUSION**

For the foregoing reasons, it is maintained that the Examiner's rejections of claims 1-15, 38 and 40-42 were therefore in error. Accordingly, appellants respectfully request reversal of all rejections.

The commissioner is authorized to charge any deficiencies in fees or credit any overpayments to our Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

/Gunther O. Hanke/  
Gunther O. Hanke, Esq.  
Registration No. 32,898

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